MAY 14 2002

K020618

510K SUMMARY

Submitted by: Aalto Scientific, Ltd.
1959 Kellogg Avenue
Carlsbad, CA 92008
Tel: 760-431-7922 Fax: 760-431-6942

Contact Person: Kenneth Gauthier

Date of Summary Preparation: February 19, 2002

Device: (Trade and Common Name)

Aalto MicroHematocrit Control

Classification Name:

CFR 864.8625, Control, Hematocrit

Device to Which Substantial Equivalence is Claimed:

STI Hematachek
Separation Technology, Inc.
1096 Rainier Drive
Altamonte Springs, FLA
K964452

Statement of Intended Use:

The Aalto Scientific Micro Hematocrit Control are human blood based solutions intended to simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for hematocrit.

510(k) SUMMARY - CONTINUED

Description of the Device:

The Aalto Scientific Micro Hematocrit Controls are prepared using human blood and chemicals, including less than 0.1% sodium azide as preservative. The Aalto Scientific Micro Hematocrit Controls are for in vitro diagnostic use only. The human components used in the manufacture of the product have been tested and found to be non reactive by FDA approved methods for HIV 1/2, HbsAg HCV and HTLV 1/2.

Statement of Technological Characteristics Compared to Equivalent Device:

Intended Use: Both devices are intended to monitor the precision of methods used to measure whole blood spun hematocrit.

Form: Both devices are liquids

Matrix: Both devices use stabilized Red Blood Cells as the matrix.

Storage: Both devices can be stored and used at controlled room temperature.

Stability: Both devices can be stored for 2 years at controlled room temperature, unopened.

Kenneth Gauthier
Quality Control Manager

02.21.02

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Kenneth Gauthier
Quality Control Manager
Aalto Scientific, Limited
1959 Kellogg Avenue
Carlsbad, California 92008

MAY 14 2002

Re: k020618
Trade/Device Name: Aalto Micro Hematocrit Control
Regulation Number: 21 CFR § 864.8625
Regulation Name: Control, Hematocrit
Regulatory Class: II
Product Code: GLK
Dated: April 12, 2002
Received: April 29, 2002

Dear Mr. Gauthier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020618

Device Name: Aalto Scientific Ltd.

Micro Hematocrit Control

Indications For Use:

The Aalto Scientific Micro Hematocrit Controls are human blood based solutions intended to simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for hematocrit

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020618